正本

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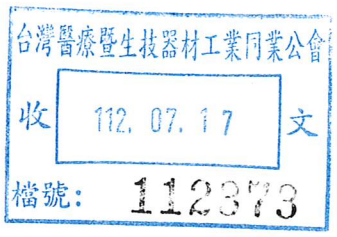
受文者：台灣醫療暨生技器材工業同業公會



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附件：廣宣及議程資料各1份

主旨：敬邀參加本署於今(112)年8月29日至31日舉辦之「2023 APEC醫療器材法規科學卓越中心研討會」，請查照轉知。

說明：

一、為促進國際法規協和，增進醫療器材標準之採用，本署以國際醫療器材主管機關論壇(IMDRF)之符合性評鑑文件為主軸，規劃於112年8月29日至31日假張榮發國際會議中心辦理旨揭研討會。邀請國內外專業人士擔任課程講師，分享醫療器材分類分級、上市前審查採用國際標準之經驗。此外，將安排以案例研究之方式針對醫療器材分類分級、安全性與功效性之基本規範及其應用進行討論。

二、檢附該研討會之廣宣及議程資料，為利強化我國產官學研各界與各國學員之交流互動，敬邀派員參與。

三、本會議係以英文進行授課及分組討論，報名者應具備適當英文能力，如報名人數超出預期，本署保留篩選之權力。

四、本研討會委請財團法人工業技術研究院協助執行，報名網址：https://tfdamdcoe.itri.org.tw/Registration.html。聯絡人及電話：工業技術研究院量測技術發展中心郭乃瑋博士(03)574-3807。

正本：台灣醫療暨生技器材工業同業公會、中華民國醫療器材商業同業公會全國聯合會、台北市美國商會醫療器材委員會、歐洲在台商務協會醫療器材委員會、台北市日僑工商醫藥品部會醫療器材委員會、中華民國生物醫學工程學會

副本：

署長吳秀梅

衛生福利部
食品藥物管理署
FDA Taiwan Food and Drug Administration

APEC
Asia-Pacific
Economic Cooperation

2023 APEC 醫療器材法規科學卓越中心研討會
Medical Devices Regulatory Science Center of Excellence Workshop

Date | August 29 – 31, 2023

Venue | Chang Yung-Fa Foundation International Convention Center

- Address: No.11, Zhongshan South Road, Taipei City

Target Audience

- Regulators from APEC member economies and non-member economies
- Industry managers (or equivalent position) who have experience in product application submission
- Academic researchers or industry managers who have experience in product development

Program Overview

- Online and self-paced learning to develop knowledge base in advance of training
- 3-day training designed with lectures, group discussions, and case studies
- Manufacturing site visit for regulators

Travel & Accommodation

- Limited funding available for regulators from travel-eligible economies

Contact Information

- ITRI Secretariat at TFDAMDCOE@gmail.com

CoE Hosting Institution

- Taiwan Food and Drug Administration

Co-Organizer

APEC Asia-Pacific Economic Cooperation

Planning Committee

Pmda JIRA AdvaMed TMDIA 台灣醫療器材生技暨材工業同業公會 TAMTA 財團法人醫藥品查驗中心 Center for Drug Evaluation, Taiwan 工業技術研究院 Industrial Technology Research Institute

Full Agenda of 2023 APEC Medical Devices CoE Workshop (Day 1 – Aug. 29 Tue.)

Time	Topic	Speaker
09:00-09:30	Registration	
09:30-09:40	Opening Remarks	**TFDA:** **Dr. Shou-Mei Wu** Director General, Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare (MOHW), Chinese Taipei **APEC RHSC MD PWA Co-Champion:** **Dr. Kinue Nishioka** Division Director, Division of Asia II, Office of International Programs, Pharmaceuticals and Medical Devices Agency (PMDA), Japan
09:40-09:50	Group Photo	
Introduction of Workshop		
09:50-10:00	Roadmap and Core Curriculum of Medical Device PWA	**APEC RHSC MD PWA Co-Champion:** **Ms. Miwa Kanematsu** Principal Coordinator, Division of Asia II, Office of International Programs, PMDA, Japan
10:00-10:10	Introduction of TFDA CoE Training Program	**Mr. Hsiu-Te Lin** Section Chief, Division of Medical Devices and Cosmetics, TFDA, MOHW, Chinese Taipei
Current Harmonization Status of Pre-Market Regulation in Each Economy		
10:10-10:40	• Introduction of Medical Device Registration in Each Economy	• 15 mins per economy
10:40-10:55	Coffee Break	
10:55-11:55	• Introduction of Medical Device Registration in Each Economy	• 15 mins per economy
11:55-12:10	Panel Discussion (Q&A)	
12:10-13:30	Lunch	
13:30-14:30	● Icebreaker Activities	
14:30-15:00	● **Medical Device & In Vitro** Diagnostic **Device Definition & Classification Session** • Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device' (GHTF/SG1/N071:2012) • Principles of Medical Device	**Dr. Shan-Hui Liao** Senior Engineer, Office of Medical Device Evaluation, Center for Measurement Standards, Industrial Technology Research Institute (ITRI), Chinese Taipei

	Classification (GHTF/SG1/N77:2012) • Principles of In Vitro Diagnostic (IVD) Medical Devices Classification (IMDRF/IVD WG/N64FINAL:2021)	
15:00-15:20	Coffee Break	
15:20-16:40	• Definition and Classification Practice • Presentation (Q&A)	**Dr. Shan-Hui Liao** Senior Engineer, Office of Medical Device Evaluation, Center for Measurement Standards, ITRI, Chinese Taipei
17:30-19:30	Welcome Reception	

***Morning sessions will be open to public**

Full Agenda of 2023 APEC Medical Devices CoE Workshop (Day 2– Aug. 30 Wed.)

Time	Topic	Speaker
Medical Device Session		
08:30-09:00	Registration	
09:00-09:30	● **Medical Device Session** • Principles of Conformity Assessment for Medical Devices (GHTF/SG1/N78:2012) • Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices(IMDRF/GRRP WG/N47FINAL:2018) • Case Study 1: Infusion set	**Dr. His-Yi Yen** Senior Reviewer, Division of Medical Devices, Center for Drug Evaluation (CDE), Chinese Taipei
09:30-10:40	• Group Discussion	
10:40-11:00	Coffee Break	
11:00-12:00	• Group Presentation (Q&A)	**Dr. His-Yi Yen** Senior Reviewer, Division of Medical Devices, CDE, Chinese Taipei
12:00-13:30	Lunch	
In Vitro Diagnostic Device Session		
13:30-14:00	● **In Vitro Diagnostic Device Session** • Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices (GHTF/SG1/N046:2008) • Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (IMDRF/GRRP WG/N47FINAL:2018) • Case Study 2: Influenza Virus Antigen Detection Test System	**Mr. Shang-Ching Lin** Assistant Technical Specialist, Division of Medical Devices and Cosmetics, TFDA, MOHW
14:00-15:10	• Group Discussion	
15:10-15:30	Coffee Break	
15:30-16:30	• Group Presentation (Q&A)	**Mr. Shang-Ching Lin** Assistant Technical Specialist, Division of Medical Devices and Cosmetics, TFDA, MOHW
16:30	Adjourn	

Full Agenda of 2023 APEC Medical Devices CoE Workshop (Day 3 – Aug. 31 Thu.)

Time	Topic	Speaker
Optimizing Standards for Regulatory Use Session		
08:30-09:30	Registration	
09:30-10:10	• Optimizing Standards for Regulatory Use (IMDRF/Standards WG/N51FINAL:2018) • Q&A	**Mr. Naoki Morooka** Senior Manager, Quality Assurance Dept., Medical Systems Division, Shimadzu Corporation, Japan
10:10-10:25	Coffee Break	
Expectations from the Workshop and Next Steps		
10:25-10:40	Expectations from the Workshop and Next Steps • TFDA (3 mins) • APEC RHSC MD PWA Co-Champion (3 mins) • APEC RHSC MD PWA Sub-Champions (3 mins each) • Members of planning committee or Participants (2 mins each)	**TFDA** **Dr. Hwei-Fang Cheng** Deputy Director General, Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare (MOHW), Chinese Taipei **MD PWA Co-Champion** **Dr. Kinue Nishioka** Division Director, Division of Asia II, Office of International Programs, PMDA, Japan **MD PWA Sub-Champion**
10:40-10:50	Certificate Award Ceremony	**Dr. Hwei-Fang Cheng** Deputy Director General, Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare (MOHW), Chinese Taipei
10:50-10:55	Group Photo	
10:55-11:00	Closing Remarks	**Dr. Hwei-Fang Cheng** Deputy Director General, Taiwan Food and Drug Administration (TFDA), Ministry of Health and Welfare (MOHW), Chinese Taipei
11:00-13:00	Lunch	
13:00-17:00	• Manufacturing Site Visit	Regulators only